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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1643

NOTIFICATION DATE	DELIVERY MODE
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01/09/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/559,994	Applicant(s) THOMPSON ET AL.	
	Examiner CHRISTOPHER H. YAEN	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,9,38-43 and 63 is/are pending in the application.
- 4a) Of the above claim(s) 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,9,38-41,43 and 63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/11/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group II (claims 3,9,38-43, and 63) in the reply filed on 5/27/08 is acknowledged. Applicant has further elected the species of a peptide having anti-neoplastic activity (claim 41) for initial prosecution on the merits.
2. Claims 1-2,4-8,10-37,and 44-62 are canceled without prejudice or disclaimer.
3. Claims 3,9,38-43, and 63 are pending, claim 42 is withdrawn as being drawn to non-elected subject matter.
4. Claims 3,9,38-41, 43, and 63 are examined on the merits.
5. The Information Disclosure Statement filed on 1/11/2006 is acknowledged and considered. A signed copy of the IDS is attached hereto.

Claim Rejections - 35 USC § 112, 1st paragraph

6. Claims 3,9,38,39,40,41,43, and 63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A WRITTEN DESCRIPTION REJECTION.

The written description in this case only sets forth an isolated protein of SEQ ID No: 4 or a polypeptide encoded by a nucleic acid sequence of SEQ ID No:3 and therefore the written description is not commensurate in scope with the claims which read on polypeptides encoded by nucleotide sequences (1) which hybridize under moderate stringency conditions or (2) derived by in vitro mutagenesis of SEQ ID No: 3.

Art Unit: 1643

Moreover, the written description is also not commensurate in scope to the claims which read on sequences which are made of "at least a portion of" or an "active portion" of a polypeptide of SEQ ID No: 4.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the claimed genus or by describing structural features common to that genus that "constitute a substantial portion of the genus." See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus."

The court has since clarified that this standard applies to compounds other than cDNAs. See *University of Rochester v. G.D. Searle & Co., Inc.*, F.3d, 2004 WL 260813, at 9 (Fed.Cir.Feb. 13, 2004). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genus. That is, the specification provides neither a representative number of mutagenic in vitro generated nucleotide sequences (such as variants or

Art Unit: 1643

sequences which are capable of hybridizing under moderate stringency conditions) that encompass the structural and/or functional requirements of genus, nor has the specification described which portions of the peptide of SEQ ID No: 4 which are "at least" required to maintain the desired activity of SEQ ID No: 4. Further, the genus is highly variant and inclusive of numerous structural variants between genus members.

Per the Enzo court's example, (*Enzo Biochem, Inc. v. Gen-Probe Inc.*, 63 USPQ2d 1609 (CA FC 2002) at 1616) of a description of an anti-inflammatory steroid, a steroid couched "in terms of its function of lessening inflammation of tissues" which, the court stated, "fails to distinguish any steroid from others having the same activity or function" and the expression of "an antibiotic penicillin" fails to distinguish a particular penicillin molecule from others possessing the same activity and which therefore fails to satisfy the written description requirement. Similarly, the claim does not recite a functional characteristic of the claimed genus which can be used to distinguish them from the large number of species comprising the specific structural requirements recited in the claims. The disclosure fails to describe common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of the SEQ ID Numbers disclosed in the specification is insufficient to describe the genus. The general knowledge and the level of skill in the art do not supplement the omitted description because specific, not general, guidance is needed.

In deciding *The Regents of the University of California v. Eli Lilly*, 43 USPQ2d 1398 (CAFC 1997), the Federal Circuit held that a generic statement that defines a genus of nucleic acids *by only their functional activity* does not provide an adequate written description of the genus. The Court indicated that while applicants are not required to disclose every species encompassed by a genus, the description of a genus

Art Unit: 1643

is achieved by the recitation of a precise definition of a representative number of members of the genus, such as by reciting the structure, formula, chemical name, or physical properties of those members, rather than by merely reciting a wish for, or even a plan for obtaining a genus of molecules having a particular functional property. The recitation of a functional property alone, which must be shared by the members of the genus, is merely descriptive of what the members of genus must be capable of doing, not of the substance and structure of the members.

“[G]eneralized language may not suffice if it does not convey the detailed identity of an invention.” *University of Rochester v. G.D. Searle Co.*, 69 USPQ2d 1886 1892 (CAFC 2004).

Furthermore, the Federal Circuit has decided that a patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated. See *Noelle v. Lederman*, 69 USPQ2d 1508 1514 (CA FC 2004) (citing *Enzo Biochem II*, 323 F.3d at 965; *Regents*, 119 F.3d at 1568). In this instance, as in that, there is no language that adequately describes with the requisite degree of particularity necessary to satisfy the written description requirement the genus of structurally variable polypeptides encoded by nucleic acid sequences which are generated in vitro by mutagenesis as claimed. Again, a description of what a material does, rather than of what it is, does not suffice to describe the claimed invention.

Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Claim Rejections - 35 USC § 112, 1st paragraph

7. Claim 38 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 38 is drawn to a vaccine comprising the peptide of claim 3. However, the specification provides insufficient guidance and objective evidence that a vaccine formulation would predictably invoke a preventative anticancer or immunotherapeutic response. The specification provides no guidance on the administration of the claimed vaccine for the purposes of prevention of a disease in vivo or in vitro.

The factors to be considered in determining whether undue experimentation is required are summarized in *re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404).

The goal of tumor vaccination is the induction of tumor immunity to prevent tumor recurrence and to eliminate residual disease. However, Ezzell (J. NIH Res, 1995, 7:46-49) reviews the current thinking in cancer vaccines and states that tumor immunologists are reluctant to place bets on which cancer vaccine approach will prove effective in the

Art Unit: 1643

long run (see the entire document, particularly last paragraph) and further states that no one is very optimistic that a single peptide will trigger an immune response strong enough to eradicate tumors or even to prevent the later growth of micrometastases among patients whose tumors have been surgically removed or killed by radiation or chemotherapy (p 48, paragraph 6). In addition, Spitler (Cancer Biotherapy, 1995, 10:1-3) recognizes the lack of predictability of the nature of the art when she states that "Ask practicing oncologists what they think about cancer vaccines and you're likely to get the following response: "cancer vaccines don't work". Ask a venture capitalist or the director of product development at a large pharmaceutical company and you're likely to get the same response." (p 1, paragraph 1). Further, Boon (Adv Can Res, 1992, 58:177-210) teaches that for active immunization in human patients we have to stimulate immune defenses of organisms that have often carried a large tumor burden. Establishment of immune tolerance may therefore have occurred and it may prevent immunization and several lines of evidence suggest that large tumor burdens can tolerate or at least depress the capability to respond against the tumor (p. 206, paragraph 2). There is no suggestion in the specification that the use of the claimed peptide would be useful as a vaccine.

DeGrujil et al (Nature Medicine, 5410): 1124-1125, Oct. 1999) state that a variety of anti-tumor vaccine trials have been undertaken and in spite of the large number of these trials, and the plethora of distinct approaches investigated, there has been little evidence of clinical efficacy. In fact, vaccine compositions would encompass all of the problems associated with treating cancer, as well as additional obstacles such as preventing the events that lead to transformation of a normal cell into a cancer cell including preventing genetic mutation, and immortalization.

In view of the teachings above, and the lack of guidance and or exemplification in the specification, at the time the application was filed it would not have been predictable for of skill in the art to use the vaccine formulations as contemplated in the disclosure. Thus, it would require undue experimentation by one of skill in the art to practice the invention as claimed.

Claim Rejections - 35 USC § 112, 1st paragraph

8. Claims 3,9,38,39,40,41,43, and 63 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for (i) an isolated peptide of SEQ ID No: 4, (ii) a peptide sequence encoded by a nucleic acid molecule of SEQ ID No: 3 or a nucleotide sequence which is completely complementary thereto, it does not reasonably provide enablement for a vaccine composition comprising a portion of seq id 4, a method of treating comprising the administration of an “active portion” of SEQ ID No: 4, nor an isolated polypeptide encoded by a nucleic acid capable of hybridizing under moderate stringency conditions to SEQ ID No:3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *Ex parte* Forman, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The claims are drawn in part to a polypeptide encoded by a nucleic acid molecule capable of hybridizing under moderate stringency conditions to SEQ ID No: 3, nucleotide sequences which are derived from mutagenesis of SEQ ID No: 3, vaccines comprising a portion of SEQ ID No: 4, and methods of treating using an active portion of SEQ ID No: 4. This encompasses a plethora of polynucleotides that are able to hybridize under moderate conditions to SEQ ID NO:3, as well as a plethora of sequences some of which may no longer bear the core structural sequence of SEQ ID No: 3 after mutagenesis. In addition, the claims also encompass a wide array of sequences of SEQ ID No: 4 any of which may qualify as a portion or an active portion.

The specification teaches that polynucleotides of the invention capable of selectively hybridizing to the DNA of SEQ ID No:3 will be generally at least 80%. One cannot extrapolate the teaching of the specification to the scope of the claims because the specification does not provide teachings or working examples which would provide sufficient guidance to allow one of skill in the art to use and or make the multitude of polynucleotide sequences encompassed by the scope of the claims. Further, the hybridization conditions as disclosed by the specification are not limiting and thus the claims read on the full range of conditions from low to highly stringent and thus the claimed hybridized polynucleotides read on polynucleotides that range from those that lack significant complementarity to those that are completely complementary to the claimed complementary polynucleotide. In addition, the specification does not define a complement in a limiting way. As conventionally understood in the art and as taught by US Patent No. 5,912,143, (filed 1996) complementarity is the natural binding of polynucleotides under permissive conditions wherein complementarity between two single-stranded molecules may be "partial", in which only some of the nucleic acids

Art Unit: 1643

bind, or it may be complete when total complementarity exists between the single stranded molecules (column 5, lines 19-32). Thus, it is clear that the claims, as broadly written, read on complements that contain even a single hybridizing residue. Thus, the scope of the claims encompass a multitude of complementary polynucleotides, which can be used as hybridizing probes, which are complementary to polynucleotides that share neither structural nor functional properties with a polynucleotide of SEQ ID No:3. Further, the scope of the claims encompasses any polynucleotide with any degree of complementarity to SEQ ID No:3 or a part thereof. Clearly, it would be expected that a substantial number of these polynucleotides or the polynucleotides that hybridize to said complementary polynucleotides encompassed by the claims **would not** share either structural or functional properties with the claimed polypeptide encoded by the nucleic acid molecule of SEQ ID No:3. Likewise, the sequences which are derived by mutagenesis from SEQ ID No: 3 also encompass a substantial number of polynucleotide sequences which require an initial sequence similarity to SEQ ID No: 3. The end result of such mutagenic sequences encompass sequences which share little to no similarity in function or characteristics to SEQ ID No: 4.

With regard to protein sequences which are drawn to a portion of SEQ ID No: 4 or an active portion of SEQ ID No: 4, these encompass fragments derived from SEQ ID No: 4. The specification has not defined which portion of those sequences are required for the claimed prophylactic or treatment activities that the claimed protein sequence is alleged to provide. In the absence of guidance in the specification, those of skill in the art would be left to experiment to determine which portions of the claimed protein sequence are needed for the claimed functional activities of prevention or treatment as claimed.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 3,9,38-41,43, and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Racie-Collins (WO 00/59938). Racie-Collins *et al* teach a sequence which is 99.7% identical to SEQ ID No: 4 (see Fig. 1) as well as methods of using the claims peptide in the treatment of disease (see pg 6, for example). The reference also teaches a nucleotide sequence which would hybridize under moderate stringency because the nucleotide sequence is substantially similar to that of SEQ ID No: 3 (see Fig. 2).

```
Query Match          99.7%;  Score 1349;  DB 3;  Length 242;
Best Local Similarity 99.6%;  Pred. No. 6.7e-130;
Matches 241;  Conservative 1;  Mismatches 0;  Indels 0;  Gaps 0;

Qy      1  MALKNKFSC LWILGLCLVATTSSKIP SITDPHFIDNCIEAHNEWRGKVNP PAADM KYMIW 60
      |||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      1  MALKNKFSC LWILGLCLVATTSSKIP SITDPHFIDNCIEAHNEWRGKVNP PAADM KYMIW 60

Qy     61  DKGLAQMAKAWANQCKFEHNDCLDKSYKCYAAFEYVGENIWLGGIKSFTPRHAITAWYNE 120
      |||||:|||||||||||||||||||||||||||||||||||||||||||||||||
Db     61  DKGLAKMAKAWANQCKFEHNDCLDKSYKCYAAFEYVGENIWLGGIKSFTPRHAITAWYNE 120

Qy    121  TQFYDFDSLSCSRVCGHYTQLVWANSFYVGC AVAMCPNLGGASTAIFVCNYGPAGNFANM 180
      |||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db    121  TQFYDFDSLSCSRVCGHYTQLVWANSFYVGC AVAMCPNLGGASTAIFVCNYGPAGNFANM 180

Qy    181  PPYVRGESCSLCSKEEKC VKNLCRTPQLIIPNQNPFLKPTGRAPQQTAFNPFSLGFLLLR 240
      |||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db    181  PPYVRGESCSLCSKEEKC VKNLCRTPQLIIPNQNPFLKPTGRAPQQTAFNPFSLGFLLLR 240

Qy    241  IF 242
      ||
Db    241  IF 242
```

Figure 1. Alignment for SEQ ID No: 4.

Art Unit: 1643

Query Match		93.5%;	Score 820.4;	DB 3;	Length 880;
Best Local Similarity		99.9%;	Pred. No. 3.5e-209;		
Matches 821;		Conservative 0;	Mismatches 1;	Indels 0;	Gaps 0;
Qy	1	CATCCTCCGCATCCTCCACATCCTTCCATGGCTCTGAAAGAATAAAATTCAGTTGTTTATGG	60		
Db	23	CATCCTCCGCATCCTCCACATCCTTCCATGGCTCTGAAAGAATAAAATTCAGTTGTTTATGG	82		
Qy	61	ATCTTGGGTCTGTGTTTGGTAGCCACTACATCTTCCAAAATCCCATCCATCACTGACCCA	120		
Db	83	ATCTTGGGTCTGTGTTTGGTAGCCACTACATCTTCCAAAATCCCATCCATCACTGACCCA	142		
Qy	121	CACTTTATAGACAACTGCATAGAAAGCCCAACAAGAAATGGCGTGGCAAAGTCAACCCTCCC	180		
Db	143	CACTTTATAGACAACTGCATAGAAAGCCCAACAAGAAATGGCGTGGCAAAGTCAACCCTCCC	202		
Qy	181	GCGGCCGACATGAAATACATGATTTGGGATAAAAGGTTTAGCACAGATGGCTAAAGCATGG	240		
Db	203	GCGGCCGACATGAAATACATGATTTGGGATAAAAGGTTTAGCAAAGATGGCTAAAGCATGG	262		
Qy	241	GCAAAACCAAGTGCAAAATTTGAACATAAATGACTGTTTGGATAAAATCATATAAATGCTATGCA	300		
Db	263	GCAAAACCAAGTGCAAAATTTGAACATAAATGACTGTTTGGATAAAATCATATAAATGCTATGCA	322		
Qy	301	GCTTTTGAATATGTTGGAGAAAAATATCTGGTTAGGTGGAATAAAGTCATTACACCAAGA	360		
Db	323	GCTTTTGAATATGTTGGAGAAAAATATCTGGTTAGGTGGAATAAAGTCATTACACCAAGA	382		
Qy	361	CATGCCATTACGGCTTGGTATAAATGAAACCCAATTTTATGATTTTGATAGTCTATCATGC	420		
Db	383	CATGCCATTACGGCTTGGTATAAATGAAACCCAATTTTATGATTTTGATAGTCTATCATGC	442		
Qy	421	TCCAGAGTCTGTGGCCATTATACACAGTTAGTTTGGGCCAATTCATTTTATGTCGGTTGT	480		
Db	443	TCCAGAGTCTGTGGCCATTATACACAGTTAGTTTGGGCCAATTCATTTTATGTCGGTTGT	502		
Qy	481	GCAGTTGCAATGTGTCCTAACCTTGGGGGAGCTTCAACTGCAATATTTGTATGCAACTAC	540		
Db	503	GCAGTTGCAATGTGTCCTAACCTTGGGGGAGCTTCAACTGCAATATTTGTATGCAACTAC	562		
Qy	541	GGACCTGCAGGAAAATTTTGCAAAATATGCCTCCTTACGTAAGAGGAGAATCTTGCTCTCTC	600		
Db	563	GGACCTGCAGGAAAATTTTGCAAAATATGCCTCCTTACGTAAGAGGAGAATCTTGCTCTCTC	622		
Qy	601	TGCTCAAAAAGAAAGAGAAATGTGTAAAGAACCCTCTGCAGGACTCCACAACCTTATTATACCT	660		
Db	623	TGCTCAAAAAGAAAGAGAAATGTGTAAAGAACCCTCTGCAGGACTCCACAACCTTATTATACCT	682		
Qy	661	AACCAAAAATCCATTTCTGAAGCCAACGGGGAGAGCACCTCAGCAGACAGCCTTTAATCCA	720		
Db	683	AACCAAAAATCCATTTCTGAAGCCAACGGGGAGAGCACCTCAGCAGACAGCCTTTAATCCA	742		
Qy	721	TTCAGCTTAGGTTTCTTCTTCTTGAGAATCTTTAATGTCATTTATATACAAAAGAAATT	780		
Db	743	TTCAGCTTAGGTTTCTTCTTCTTGAGAATCTTTAATGTCATTTATATACAAAAGAAATT	802		
Qy	781	CTCAAAATGTTAAAAATAAGGAATAGTTTATTGCTTAATATAA	822		
Db	803	CTCAAAATGTTAAAAATAAGGAATAGTTTATTGCTTAATATAA	844		

Figure 2. Alignment for SEQ ID No: 3.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER H. YAEN whose telephone number is (571)272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher H Yaen/
Primary Examiner, Art Unit 1643